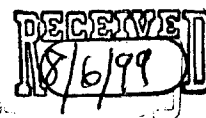




August 3, 1999



Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, DC 20204

5885

AUG 13 P2 04

RE: Ricola® Herbal Health™ Prostate Formula

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Ricola, Inc. ("Ricola"), Morris Plains, New Jersey 07950, hereby notifies the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label that bears statements of nutritional support. Ricola is the distributor of this product.

The dietary supplement for which the statements are made is Ricola® Herbal Health™ Prostate Formula. Per serving size of two tablets, the supplement contains: Saw palmetto berry standardized extract, 320 mg; Purified soy phytosterols, 120 mg; Prostate support phytonutrient blend, 200 mg (flower pollen extract, tomato lycopene concentrate, pygeum bark and stinging nettle root; Bio-enhancing herbal blend, 25 mg (extracts of hyssop, lemon balm leaf, peppermint leaf, sage leaf and thyme leaf); Vitamin E, 60 IU; Zinc, 20 mg; Copper, 2 mg; and Selenium, 200 mcg.

The statements of nutritional support for this product read as follows:

- Ricola® Herbal Health™ Prostate Formula is a multi-dimensional approach to maintaining normal prostate health and function.
- Research-supported levels of standardized saw palmetto are reinforced with protective soy compounds, phytonutrients, natural vitamin E and minerals essential to prostate health.
- This advanced formula is further enhanced with a special blend of healthful Ricola herbs.

A copy of the outer package and inner-container label for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

Ricola USA, Inc.
51 Gibraltar Drive
Morris Plains, NJ 07950
Phone: 973-984-6811 • 800-323-9073
Fax: 973-984-6814
E-mail: info@ricolausa.com

973-0102

LET 4058

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
August 3, 1999
Page 2

Ricola certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the DSHEA; and that the information contained in this notice is complete and accurate.

Sincerely,

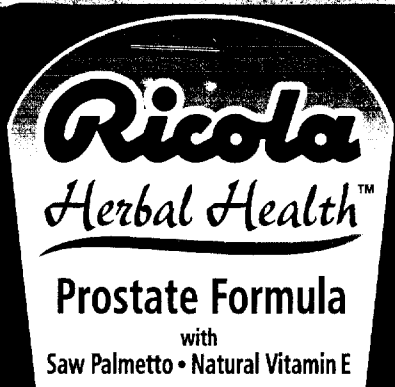
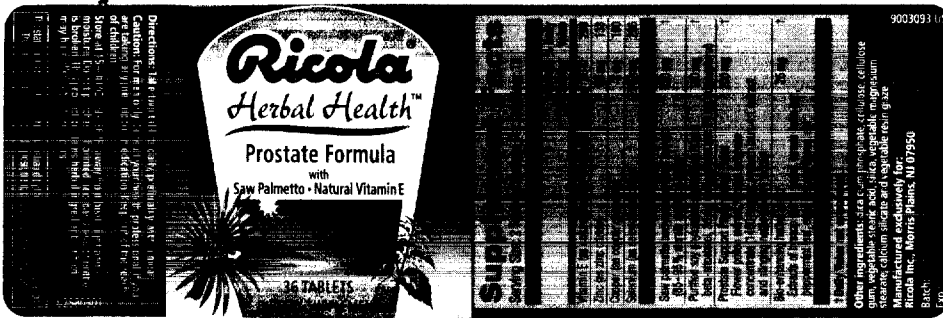
A handwritten signature in black ink, appearing to read "Dan Thomas", written in a cursive style.

Dan Thomas
President

Enclosure

Original plus two copies enclosed

Ricola® Herbal Health™ Prostate Formula



For more than sixty years the world has trusted the Ricola name for herbal products of the highest quality and purity. Today, the tradition continues with Ricola® Herbal Health™ supplements. Meticulously crafted by Swiss experts, these balanced formulas skillfully combine research-recommended levels of highly standardized botanicals with essential vitamins and minerals. Each formula is further enhanced for optimum digestibility with an exclusive blend of healthful Ricola herbs.

Ricola® Herbal Health™ dietary supplements also available:

- Active Memory Formula
- Heart Formula
- Immune Formula
- Women's Formula
- Antioxidant Formula
- Mood Formula
- Night Time Formula

For comments or questions on Ricola herbal supplements, call 1-800-323-9073, or visit us at www.ricolausa.com.

Directions: Take two tablets daily, preferably with a meal.

Caution: For men only. Consult your health professional if you are taking any prescription medication. Keep out of the reach of children.

Store at 15–30°C (59–86°F) away from heat, light and moisture. Do not purchase if printed neckband seal of bottle is broken. This product contains herbal ingredients, which may have distinct natural odors.

Ricola® Herbal Health™ Prostate Formula is a multi-dimensional approach to maintaining normal prostate health and function. Research-supported levels of standardized saw palmetto are reinforced with protective soy compounds, phytonutrients, natural vitamin E and minerals essential to prostate health. This advanced formula is further enhanced with a special blend of healthful Ricola herbs.

The statements herein have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

